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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,580	04/12/2004	Scott A. Entenman	AUGA07000021	2643
Terrance A. Meador, Esq. INCAPLAW Suite K 1050 Rosecrans Street San Diego, CA 92106			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
DATE MAILED: 02/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,580

Applicant(s)

ENTENMAN ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4-23-04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: In line 3 of page 13 of the specification, the "3-way connector" should be labeled 114, and the "drip chamber" should be labeled 115. Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: the phrase "near the first and second edges" should be changed to "near the first and second sides" as the word edges has no antecedent basis. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 3-9, 11-13, 16-20 and 22-35 of copending Application No. 10/214966. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have changed a single U-shaped tensioning rod into two rods/rails and it would have been an obvious choice to eliminate the closed arcuate handle and leave that section of the cassette solid as a stiffening portion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-10, 13-17, 19, 20, 27 are rejected under 35 U.S.C. 103(a) as being anticipated by Jusiak et al. (US Patent No. 6,901,216) in view of Jordan et al. (US Patent No. 5,875,282). Jusiak discloses the device substantially as claimed including a fluid warming cassette (Fig. 1) comprising: a first sheet (Fig. 2, 32) and a second sheet (34), made from polyethylene, joined together to form a fluid container with a periphery,

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the periphery having a proximal end, a distal end and first and second sides there between; a fluid channel (Fig. 1, 21) in the fluid container between the first sheet and the second sheet; first and second rails (30a and 30b), inside the periphery, near the first and second sides, respectively; and a planar stiffener (42), separate from the first and second rails, disposed between the first sheet and the second sheet (col. 3, lines 27-40 and lines 47-53), and between the first and second rails, near the proximal end. Jusiak also discloses that the stiffener has a first elongate portion extending between the first and second rails (Fig. 3, 42) and a second portion (Fig. 4b, the portion that curves out) protruding from the first portion in the direction of the distal end. Jusiak also discloses that the rails have shapes for keying the insertion of the cassette into a warming unit (col. 3, lines 59-61). Jusiak further discloses that the serpentine fluid channel (21) is disposed between the first and second rails (28a and 28b). Jusiak further discloses that the stiffener forms a handle portion (either 42 or the portion curving out in Fig. 4b could be used as a handle). Jusiak further discloses that the cassette has a label surface (66). Jusiak also discloses first (24) and second (26) ports in fluid communication with the fluid channel (21). Jusiak further discloses that the rails can be made of any conventional material, such as plastic or metal (col. 3, lines 63-65). Jusiak also discloses that the stiffener can be made of any polymeric material or metal (col. 4, lines 31-36).

Claim 29-31 is rejected under 35 U.S.C. 102(e) as being anticipated by Jusiak et al. (US Patent No. 6,901,216). Jusiak discloses a fluid warming cassette comprising: a flexible fluid container with two edges and two ends (Fig. 1); a fluid channel (21) in the

fluid container; first and second rails (30a and 30b) disposed in the fluid container, near first and second edges of the fluid container, respectively; and a handle portion (20) formed near an end of the fluid container by sandwiching a planar piece in the fluid container (col. 4, lines 37-41).

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Jusiak (US Patent No. 5,875,282). Jusiak discloses the process including: positioning a first and second rail parallel to each other enclosed by a base sheet and a cover sheet, and positioning a planar stiffener at an end of the sheets and between the sheets and rails and then joining the base and cover sheet to enclose the rails and the planar stiffener and forming a fluid channel (col. 3, lines 21-26, 47-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Jordan et al. (US Patent No. 5,875,282). Jusiak discloses the device substantially as claimed except for rails of multi-lateral cross section and consequently the surface supporting an arch of the first sheet. Jordan, however, discloses that the rails can be made of any shape or cross section (col. 3, lines 54-65), thus encompassing cross sections, such as rectangular, that would permit the rails to support an arch of the first sheet. Therefore it would have been obvious to one of

ordinary skill in the art at the time of the invention to have modified Jusiak with the rails with multi-lateral cross sections as taught by Jordan in order to provide rails that provide an arch with the sheet covering it and to provide different shaped rails to fit in different shaped grooves of the warming apparatus.

Claims 11, 12, 28, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Tousignant et al. (US Patent No. 5,205,348). Jusiak discloses the device substantially as claimed including ports, however, Jusiak does not disclose expressly that the ports are disposed perpendicularly to the fluid container or that they constitute insertion stops. Tousignant discloses two ports (Figs. 4-6) that are perpendicular to the fluid container. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the perpendicular ports as taught by Tousignant in order to provide cassette insertion stops.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Bakke (US Patent No. 6,608,968). Jusiak discloses the device substantially as claimed except for the stiffener being made of cardboard or cardstock. Bakke, however, discloses a fluid-warming envelope (Fig. 4, 16) with a paperboard stiffener (26) to aid in inserting the envelope into the warmer. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the paperboard stiffener as taught by Bakke, in order to provide another inexpensive material for use as a stiffener with the cassette.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Greenblatt (US Patent No. 4,707,587). Jusiak discloses the device

substantially as claimed except for each sheet being made of a plurality of layers.

Greenblatt, however, discloses a fluid warming jacket (Figs. 7 and 8, 7) in which each of the first and second sheets is made of a plurality of layers. Each sheet is made of an inner layer of plastic and an outer layer of aluminum, which are laminated together (col. 2, line 66 through col. 3, line 4). Thus, the inner layer (plastic) has a lower melting point than the outer layer (aluminum). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the laminated layers of Greenblatt in order to provide a jacket with a conductive layer and a non-reactive layer that contacts the blood.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Tousignant and further in view of Kujawski et al. (US Patent No. 4,568,330). Jusiak in view of Tousignant discloses the kit substantially as claimed including: a fluid warming cassette with fluid channel, rails, planar stiffener, and inlet and outlet ports perpendicular to the warming cassette. Jusiak in view of Tousignant, however, does not disclose expressly inlet and outlet lines, a drip chamber or a bubble trap. Kujawski discloses a fluid chilling chamber (Fig. 1, 54) which has an inlet line (52) including an inlet end (44) for receiving fluid from sources, a drip chamber (42) with an inlet coupled to the first end and an outlet coupled to the inlet port (where 52 connects to 54); and an outlet line (56) including a bubble trap (144 and 146) with an inlet coupled to the outlet port (where 54 connects to 56) and an outlet (64), and an outlet end (72) for delivering warmed fluid. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak in view of Tousignant with the inlet and

outlet lines, drip chamber and bubble trap as taught by Kujawski, in order to provide a kit that is ready for use with a patient and infusion source.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mike Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MICHAEL J. HAYES
PRIMARY EXAMINER